(12) # EUROPEAN PATENT APPLICATION

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(54) Heart valve prosthesis, method for producing a heart valve prosthesis and mould applied thereby.

(57) Heart valve prosthesis consisting of a substantially rigid
frame (1) with provided therein several synthetic membranes (2)
whereby the membrane is a fibre-reinforced matrix material,
whereby the fibres (23) are arranged parallel in the matrix
material and that the fibre material and the matrix material are
chemically identical.
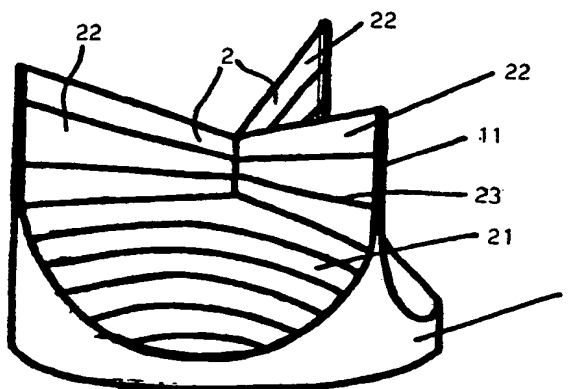
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Heart valve prosthesis , method for producing a heart valve prosthesis
and mould applied thereby.

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The invention relates to a heart valve prosthesis consisting
of a substantially rigid frame with provided therein several synthetic
10 membranes whereby the membrane is a fibre-reinforced matrix material.
The invention further relates to a method for producing a heart valve
prosthesis and to the mould applied hereby for producing a heart
valve prosthesis intended for implantation in the aorta position, and
pulmonal position consisting of a frame with three membranes provided
15 therein.
         Heart valve prostheses can be divided into three groups
viz. the mechanical artificial valves, bioprostheses whereby prepared
heart valves of animals are used and artificial membrane valve prostheses.
A mechanical heart valve is described in the Dutch patent application
20 7906506 and in the United States patent specification 3,824,629. A disad-
vantage of mechanical heart valves is that it is necessary for the
patient to use anti-coagulants, which can have disadvantageous consequences
in the long run. The mechanical valve namely is trombogeneous by nature
as the material of the valve is an adhering place for trombocytes.
25 As a result of that blood coagulates arise which may interfere with
the functioning of the valve and which may come loose and may have a
disadvantageous effect elsewhere in the body. Therefore it is necessary

for patients with a mechanical heart valve to use anti-coagulants
regularly.

With bioprostheses frequent use is made of the heart valve
of a pig but such bioprostheses have the drawback that relatively

5   soon there occurs calcification, as a result of which such a biovalve
needs to be replaced again after a number of years. Such biovalves
are suspended in a frame and are then implanted.

The present patent application relates to an
artificial membrane valve prosthesis, which aims to be an approximation

10 of the bioprosthesis concerning its operation, without the occurrence
of the drawbacks of the bioprostheses applied so far such as the calci-
fication of the membranes and the limited life time. For that
purpose use has been made of membranes made of synthetic material
suspended in a frame.

15   With regard to membrane valve prostheses a great deal of
research has already been done and results have been published. Thus
there is in Trans. Amer. Soc. Artif. Int. Organs, 1974, volume 21,
pp. 703-707, according to E.L. Gerring and others, a membrane made
of silicone rubber reinforced with polyester. Said polyester has been

20 woven and afterwards provided in the silicone rubber as reinforcement.
The valve thus obtained, known as the Oxford-valve, appeared to be
insufficiently resistant to the occurring stresses, however. Membrane
valve prostheses have been made by G. Häussinger and H. Reul as
mentioned in Biomedizinische Technik, 26 (1981) pp. 40-43, whereby

25 polyurethane, silicone rubber reinforced with a polyester web and a
specific polyurethane (Avcothane-51), which is a compound of 95%
polyurethane and 5% polydimethyl siloxane, have been compared. (On p. 41
of said literature reference the references to the specific materials
are incorrect). From the experiments carried out according to G.

30 Häussinger it became apparent that the valves made of Avcothane-51 had
the longest span of life. It has now appeared to be possible to further
improve the mechanical properties of such membrane valve prostheses.

Experiments carried out have now led to a membrane construct-
ion by starting from fibre-reinforced material according to the

35 invention and it is characterised in that the fibres are arranged
substantially parallel in the matrix material and that the fibre
material and the matrix material are chemically identical. The fibre

material and the matrix material are preferably made of polyether ure-
thane.

As the fibre material has to be more rigid than the matrix
material the basis for the preparation of the fibre material has been
5 a polyether of a lower molecular weight than for the polyether of the
matrix material and thereby polyoxy tetramethylene glycol (POTM) has
specifically been used, whereby for the preparation of the fibre material
the polyether can first be subjected to a coupling reaction to further
increase the molecular weight. The polyether urethanes are prepared in
10 two steps. First a prepolymer is prepared from a diisocyanate and a
polyether glycol in a molar compound of 2 : 1 and then the prepolymer
chains are coupled with a chain-lengthening agent such as a diamine
or diol.

The method for producing the membranes takes place in a
15 mould, which has the shape of the membranes to be formed, in which mould
the frame and the fibres are placed and by submersing and drying the
matrix material is formed around the fibres so that said fibres are
embedded in the matrix material. For that purpose a film of the matrix
material is preferably first applied to the mould, after which the
20 fibres and the frame are placed in the mould whereby the fibres are
placed substantially parallel to each other and perpendicular to the
direction in which the membranes move in practice. Then a DMF (dimethyl
formamide) solution of the matrix material is applied and the solution
dried so many times that the fibres are embedded and incorporated
25 in the matrix material so that a membrane is obtained consisting of
fibre-reinforced matrix material adhered to the frame. Such a mould
is known and described in Artificial Organs, volume 5 (suppl), 1981,
pp. 323-326 by R.J. Kiraly and others. The mould now used has been
modified as regards the specific dimensions and parameters.
30   The invention will be more fully explained with reference to
the following description and the appended drawing, in which:

Fig 1 is a diagrammatic view of a symmetric heart valve pros-
thesis with three synthetic fibre-reinforced membranes in closed
position;
35   Fig 2 shows, in a three-dimensional orthogonal coordinate
system, one sixth part of the heart valve prosthesis of fig 1, comprising
a frame leg and a half membrane and being used as an arithmetic model; and

Fig 3 illustrates the projection of a elementary division
of the half membrane of fig 2 in the plane of the coaptation area.

At the basis of the instant invention is a
design study for achieving an optimum design of a leaflet or membrane valve
5 prosthesis. With a view to cheap production the simplest possible
valve geometry and material properties of the frame and the artificial
membranes are aimed at and the membranes are connected direct to the
frame, which was chosen flexible as a starting point for the design
study, in order to approximate the properties of the natural valve
10 as much as possible and as it is apparent from the literature on
this field of the art that a rigid frame has a disadvantageous ef-
fect on the operation and the life time of a bioprosthesis, roughly
said synthetic frame and natural membranes.

The membranes are fibre-reinforced , as this is also the case
15 in the natural situation. According to the invention, however, fibres
extending substantially parallel at distance are applied in the mem-
branes.

Furthermore the frame legs (reference numeral 11 in fig 1)
have been chosen very narrow, lest they interfere with the mechanism
20 of the gradual closing of the valve.

In view of the above the influence of geometry and material
properties of the membrane valve prosthesis on the distribution of stress
in the membranes in a closed valve has been determined in the design
study.

25 Fig 1 diagrammatically illustrates the symmetric membrane
valve prosthesis according to the invention in closed position. The
membrane valve prosthesis has three synthetic leaflets or membranes 1, which are
each provided with fibres 23 extending substantially parallel to each
other. Each membrane 2 thereby comprises a free membrane portion 21,
30 which is connected to the basis of the frame 1 and a coaptation area 22,
which is connected at its ends to a respective frame leg 11. In closed
position the one half of the coaptation area 22 of a membrane 2 bears
against a corresponding half of the coaptation area of an adjacent
membrane, whilst the other half bears against a respective half of
35 the other adjacent membrane. The angles made by the coaptation areas 22
of the membranes 2 in closed position of the membrane valve prosthesis
are 120° each. According to the invention a heart valve prosthesis

preferably comprises a frame and three fibre-reinforced membranes suspended in the frame, said frame being substantially an upright, circular closed strip with three frame legs located along the strip at equal distance in the same direction, whereby the height of the
5 strip is greatest near the frame legs and each time decreases symmetrically, according to a certain curve, from two frame legs along the strip to the centre of the strip portion between the frame legs and whereby each time the coaptation portion of a membrane is connected to two adjacent frame legs and the free membrane portion is connected to
10 the strip portion of the frame enclosed by the frame legs, whereby in the closed positon of the heart valve prosthesis the coaptation portions of the membranes lie against each other and the ends of the captation portions not connected to the frame legs define a substantially straight line.
15   In fig 2 a diagrammatic view of the basic model of the membrane valve prosthesis is shown. ABE represents hereby the free membrane area 21, whilst BCDE represents the coaptation plane 22; naturally of a half membrane. The numeric model of fig 2 is analogue to that of the so-called Hancock-valve (see chapter 5 in "Tissue Heart
20 Valves", published by M. Ionescu, 1979; pp. 178-179). For the description of the geometry of the basic model the angle α, the angle β, the z-coordinate of point A(z(A)) and the length of the lines BC and DE of the aforementioned Hancock-valve of 23 mm are taken and amount to 20°, 15°, 0.5 mm, 5.1 mm and 1.9 mm respectively. With the assumption
25 that AE, BE, BC, CD and DE are straight lines and AB can be represented by:

$$z(AB) = z(A) + C_1 \, (\bar{r} \, \theta \,)^2$$

$$x^2 + y^2 = \bar{r}^2 \qquad \text{with } C_1 = \frac{z(B) - z(A)}{(\bar{r} \cdot \pi/3)^2} ;$$

30     $z(B) = 4.9$ mm; $\bar{r} = 10.82$ mm and $z(A) = 0.5$ mm
the membrane geometry has been fully described. This description for the line AB has been chosen because with this relation the geometry of AB has been fully described with one parameter (C_1), which is also univocally related to the angle α. Besides that said representation
35 can be applied to higher values of α than with the spherical description.
     Analogous to the Hancock-valve a value of 0.4 mm for the

matrix or membrane thickness d_m and a value of 1.8 N/mm² for the elastic modulus or modulus of elasticity was chosen for the basic model.

In table A, in the column with the heading " basic value ", the numeric values of the parameters indicated in said table are
5   shown. With these values of the geometric and material parameters the basic model was subjected to a pressure load   of 12 kPa effected in 10 ms.

After that the following four stress parameters were analyzed:
I) the von Mises-intensity in the membrane portions between fibres
10 to characterise the breaking-down action of the membrane;
II) the tensile stress in the fibres corresponding with the breaking of the fibres;
III) the negative values of the minimum principal stress in the coaptation area which represent the wrinkling or creasing of the
15 membrane; and
IV) the magnitude of the shear force per unit of length between fibre and membranes or matrix as a measure of the tearing loose from the membrane of the fibres.

The results of this analysis will now be discussed with
20 reference to fig 3. The highest values for the von Mises-intensity are found near point B, along the line BC and in the centre of the membrane (from B to line AE), viz. values from 0.12 to over 0.16 (N/mm²). With a further study of the influence of the geometry and material parameters the points 1-4 in fig 3 will be considered with regard to
25 the influence of said parameters on the distribution of stress in the membrane.

For the fibres in the coaptation area the maximum value for the tensile stress in the fibres is found at their fixation to the frame, whereby said value decreases into the direction of the centre
30 of the valve. The tensile stress in the fibres in the free membrane area is substantially constant along the entire length of the fibres. For a further observation the membrane points a and b of fig 3 will be considered.

The largest negative principal stress is found near the
35 fixation of the membrane to the frame in the coaptation area. Points 3 and 5 in fig 3 will be taken as representative points for a further analysis. The shearing force per unit of length between fibre and

membrane has been calculated for the arbitrary system points 26 in the free membrane area and 41 in the coaptation area and amount to 0.0006 and 0.021 N/mm respectively.

The maximum tensile stress in the fibres was lower than
5   0.5 N/mm², whilst the minimum principal stress in the membranes was smaller than - 0.07 N/mm².

Thereupon, in order to obtain a global insight, the parameters enumerated in table A were varied between the minimum and maximum values illustrated in the relevant columns, whereby most of these
10 values were chosen rather arbitrarily, yet in such a manner that differences in stresses were expected.

One by one the parameters were varied, without changing the remaining parameters mentioned, between said minimum and maximum value and, in order to obtain a quantitative comparison of the stress
15 situations for the various adjustments of the parameters, points were chosen in the valve geometry where there was the worst distribution of stress in the basic model. Referring to fig 3 the von Mises-intensity was therefore determined for the points 1,2,3 and 4, the tensile stress of the fibres was given for the fibre points a and b, the minimum
20 principal stress was given for the points 3 and 5 and the shearing force for the system points 26 and 41.

The aforementioned membrane thickness and modulus of elasticity of the membranes were not varied. They were chosen to ensure lower bending stresses in the membranes, which is considered to be of great
25 importance with regard to the opening and closing action of the membranes. On the other hand a low value of the membrane thickness is bad because of the desired strength in the closed position, whilst the modulus of elasticity of the membranes cannot be decreased much because of manufacturing reasons, when e.g. polyurethanes are used. As applicable
30 values for said parameters the intervals $0.2 < d_m < 0.6$ mm and $1 < E_f < 5$ N/mm² will be taken, therefore. Table B shows the results of these calculations.

From table B it appears that the parameters that cause the greatest change in the distribution of stress are the parameters
35 d_{FR}, α, d_f, E_f and mfd.

From table B it can furthermore be read that the highest value of the von Mises-intensity in the membrane is always present

symbol	parameter	basic value	minimum value	maximum value
E_{FR}	modulus of elasticity of the frame (N/mm^2)	1582	1000	200,000
d_{FR}	frame thickness (mm)	1	0.5	2.5
α	angle in the free membrane area ($^\circ$)	20	0	60
A_{coap}	size of the coaptation area (mm^2)	38.2	19.1	76.4
d_f	fibre thickness	0.4	0.1	0.7
E_f	modulus of elasticity of the fibres (N/mm^2)	23	2.3	230
mfd	average fibre distance (mm)	1.4	1.4	∞ (no fibres)

Table A

	von Mises intensity (N/mm²)				fibres stress (N/mm)		negative values of minimum principal stress (N/mm²)		shear force per unit of length (N/mm)	
	1	2	3	4	a	b	3	5	26	41
basic model	0.222	0.147	0.158	0.133	0.47	0.44	0.096	0.049	0.0006	0.0206
E_{FR} = 1000 N/mm²	0.227	0.151	0.157	0.106	0.48	0.41	0.097	0.050	0.0003	0.0211
E_{FK} = 200,000 N/mm²	0.210	0.141	0.161	0.128	0.45	0.51	0.092	0.046	0.0009	0.0192
d_{FP} = 0.5 mm	0.219	0.118	0.088	0.027	0.33	0.05	0.000	0.016	0.0134	0.0073
d_{FR} = 2.5 mm	0.211	0.141	0.161	0.128	0.46	0.51	0.092	0.046	0.0011	0.0193
α = 0°	0.162	0.142	0.170	0.134	0.40	0.54	0.106	0.047	0.0004	0.0185
α = 60°	0.296	0.101	0.151	0.158	0.66	0.73	0.164	0.010	0.0339	0.0058
A_{coap} = 19 mm²	0.230	0.149	0.181	0.161	0.50	0.58	0.101	0.067	0.0004	0.0295
A_{coap} = 76 mm²	0.212	0.145	0.134	0.055	0.45	0.22	0.079	0.023	0.0008	0.0088
d_f = 0.1 mm	0.270	0.186	0.208	0.202	0.66	0.87	0.099	0.034	0.0205	0.0028
d_f = 0.7 mm	0.177	0.121	0.123	0.069	0.30	0.20	0.087	0.053	0.0192	0.0242
E_f = 2.3 N/mm²	0.267	0.184	0.204	0.195	0.07	0.08	0.099	0.036	0.0083	0.0073
E_f = 230 N/mm²	0.133	0.136	0.097	0.049	1.37	0.66	0.076	0.052	0.0394	0.0207
mfd = ∞	0.275	0.177	0.214	0.215	-	-	0.099	0.032	-	-
"viscous frame"	0.224	0.148	0.158	0.110	0.47	0.43	0.097	0.050	0.0006	0.0205
"elastic membrane"	0.237	0.166	0.169	0.117	0.49	0.45	0.105	0.054	0.0009	0.0220
"viscous membrane"	0.214	0.141	0.153	0.111	0.46	0.44	0.091	0.047	0.0088	0.0198

E_{FR} = modulus of elasticity of the frame

d_{FR} = frame thickness

α = angle in the free membrane area

A_{coap} = size of the coaptation area

d_f = fibre thickness

E_f = modulus of elasticity of the fibres

mfd = mean fibre distance

Table B

in point 1 and slightly less in point 3. The maximum tensile stress
in the fibre is not related to a certain fibre portion. The magnitude
of the negative minimum principal stress is usually much lower than the
van Mises-intensities. The highest negative value is usually found in
5 point 3.

The stress parameters are hardly influenced by the modulus
of elasticity of the frame material, the size of the coaptation area
and the variation of the viscous properties of the membrane and frame
material in the ranges considered. The fibre-stress only changes in
10 the coaptation area.

Finally the behaviour of the five afore-said geometry and
material parameters on the distribution of stress has been studied, where-
by mutual influencing has been taken into account.

The remaining five parameters were varied in smaller steps
15 for that purpose.

It has become apparent that with $E_{FR} = 1582$ N/mm^2, d_{FR}
is only of importance if it ranges from 0.6 to 1.4 mm. With a frame
thickness of over 1.4 mm no changes in stress are observed. With a
frame thickness between 0.6 and 1.4 mm the stresses in the coaptation
20 area (points 3,4 and b) increase with an increasing frame thickness.
The tensile stress of the fibres in the free membrane area (point a)
remains constant then, whereas the membrane stresses in the free
membrane area (point 1 and 2) decrease.

An increase of α leads to a decrease of the stresses in the
25 membrane and the fibres in the coaptation area, whereas the changes in
the free membrane area are only marginal, with the exception of the
von Mises-intensity in point 1, which increases with an increasing α .

If the fibre-thickness increases, the stresses in the membrane
and the fibres become smaller across the entire membrane.
30 Stiffening of the fibres leads to an increase of the tensile
stress in the fibres and to a decrease of the von Mises-intensity in
the membranes. Finally the membrane stresses generally show a slight
increase with an increase of the average fibre distance. Only for the
von Mises-intensity in point 2 (fig 3) a relatively discrete line is
35 found, when the smallest distance from point 2 to the nearest fibre
changes relatively discretely.

There is only a small influence of the design parameters on

the negative principal stresses. The angle α and the frame thickness d_{FR} have no influence on the shearing forces in the system points 46 and 41, whilst variation of the fibre-stiffness and fibre-thickness leads to a remarkable alteration of the shearing forces.

5   The influence of the average fibre distance on tensile stresses in the fibres and on the shear force is not given. Variation of said design parameters does not provide comparable information about alteration in tensile stress in the fibres and about alterations in shear forces, as the fibrous structure is different for the

10 various cases calculated. Besides the average fibre distance can only have a few discrete values.

      The parameter variation study was continued with the four parameters d_{FR}, α , d_f and E_f. For these parameters a statistic procedure was used for obtaining a linear model, in which linear

15 interaction terms had been incorporated.

      From this it became finally apparent that for the parameter α all stress quantities become smaller for decreasing values of α , with the exception of the von Mises-intensity in the points 3 and e and the tensile stress in fibre point b. The last-mentioned quantities,

20 however, are substantially smaller than comparable stress quantities in other points of the valve. Therefore the value of the minimum principal stress is considered a more relevant design criterion for point 3 than the von Mises-intensity at that point. Therefore the interval $0° < \alpha < 20°$ appears to be suitable as an applicable range.

25 With regard to the actual valve design a very small value of α should be avoided to prevent the membrane from giving way in the closed position.

      For the quantity $1/d^2_{FR}$ linear relations have been found, as the second order term did not contribute substantially to the linear

30 model. Most stresses show a minimum for $(1/d^2_{FR}) \rightarrow 0$, which corresponds with a rigid frame. Here the von Mises-intensity in the points 3 and 4 and the tensile stress in fibre point b show an opposite behaviour again. For a rigid frame, however, the values of those stress quantities are substantially lower than the comparable stress quantities

35 in the other points of the valve.

      It is surprising now that in agreement with the invention it was found that a rigid frame has an advantageous influence on the

distribution of stress in the valve, as a result of which a bias in
the state of the art that a rigid frame should have a disadvantageous
influence and that the natural situation viz. a flexible frame should
be preferable, is abandoned.

5   For the modulus of elasticity of the fibre material linear
relations were found as well, as the second order term did not con-
tribute substantially to the linear model. The choice of an optimum is
made very difficult because a completely different behaviour of the
10 stress quantities was found (i.e. the von Mises–intensities in
10   points 1-4, the tensile stress in the fibre points a and b, the minimum
principal stress in points 3 and 5 and the shearing force per unit of
length in system points 26 and 41).

Furthermore, starting from $\alpha = 10°$ and a rigid frame, d_f
and E_f were varied simultaneously in order to specify the fibre
15 design specifications in more detail.

E_f and d_f were varied from 10-50 N/mm^2 and 0-1 mm respectively.
(In the above α and $1/d^2_{FR}$ were varied between 0-50° and 0-25 mm^{-2}
respectively).

It has become apparent that the von Mises–intensity in the
20 membranes can be reduced by using a greater fibre stiffness. In that
case the tensile stress in the fibres shows a considerable increase.
The highest values of the minimum principal stress were found in point 3.
An increase of the fibre stiffness leads to a decrease of that stress
quantity, although the change is relatively small.
25   The shear force in node 26 is relatively high in
comparison with node 41 and substantially independent of the
fibre stiffness. The shearing force in node 41 remains small
when E_f ranges from 10 to 50 N/mm^2.

Because of that the value of E_f for the design is to be
30 chosen primarily because of its influence on the von Mises–intensity
in membranes and tensile stress in the fibres. As it is plausible that
lower membrane stresses are more important with regard to the occurrence
of the valve becoming inactive than lower tensile stress values in
the fibres, preference is given to higher values of E_f. Therefore the
35 interval $10 < E_f < 50$ N/mm^2 is chosen as an applicable range for E_f.

With relation to the choice of the fibre–thickness the
applicable values have been restricted to values lower than the matrix

thickness. The reason for this is that a thicker membrane in the area
of the fibres than between said fibres is disadvantageous with
relation to the calcification process. Besides it is not advisable
to increase the value of the membrane thickness, because of the
5 bending strains which occur during the opening and closing of the valve.
On the other hand very low values of the membrane thickness lead to
higher values of nearly all stress quantities. As a result of that the
interval $0.2 < d_f < 0.3$ mm is chosen as an applicable range for the
fibre thickness with a membrane thickness of 0.4 mm.

10   Finally a rigid frame was chosen for the specific design
situation, $\alpha = 10°$, $d_m = 0.4$ mm, $d_f = 0.25$ mm and $E_f = 50$ N/mm^2,
whilst the influence of the fibrous structure on the distribution of
stress was analyzed for various values of the average fibre distance mfd.
      The difference between the fibre-reinforced basic situation
15 and the situation without fibres (mfd = ∞) lies in the range of
20-75% for all membrane stresses. Reduction of the average fibre
distance in the case of fibre-reinforcement, however, leads to much
lower values of changes in all stress quantities (lower than 15%).
Therefore the average fibre distance is not very critical by itself.
20 As an applicable range the range $0.8 < mfd < 2.7$ mm is chosen.
      In table C the applicable ranges of the principal parameter
values and the chosen value for the design have been indicated or
summarized respectively.

25

	applicable range	value chosen
E_{FR}	1000 – rigid frame	rigid frame
d_{FR}	0.5-1.5 mm	1 mm
α	0-20°	10°
A_{coap}	19-76 mm^2	38 mm^2
d_f	0.2-0.3 mm	0.25 mm
E_f	10-50 N/mm^2	50 N/mm^2
mfd	0.8-2.7 mm	1.5 mm
d_m	0.2-0.6 mm	0.4 mm
E_m	1-5 N/mm^2	1.8 N/mm^2

Table C

The parameter values given in table C lead to a valve design that shows various great advantages. As a result of the low α -value the valve is relatively low in the first place. The great advantage of this is that the valve, implanted in the aorta position,

5 fits to the sinusses, which is important for its closing behaviour. Furthermore the valve can also be used in the mitral position, whereby a low profile is sometimes necessary, because of the lack of space in a small left ventricle. In the latter case the membrane heart valve prosthesis may have two instead of three membranes.

10 ·   A great advantage of a rigid frame is that steel can be used as frame material, as a result of which problems of the creep of the polymer of a flexible frame can be eliminated. If the frame is made of steel covered with the same material as is used for the membranes, more specifically polyurethane, the membranes may be glued to the frame,

15 which provides a solid attachment. The chosen relation of fibre stiffness and membrane stiffness is around 25 with a modulus of elasticity of the fibres of 50 N/mm^2. The values are within the range of the material parameter values of polyurethanes, which can be produced by standard synthesis techniques. Because of the use of the same material

20 for fibres and membranes, glueing of the two components will ensure a strong fibre-matrix connection. The fibres, having a diameter of 0.25 mm, can be produced by means of spinning techniques. Summarizing the valve proposed has a relatively simple design, it can be produced in a simple manner and, because of its small height, it can be applied

25 in the aorta and the mitral position.

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CLAIMS

1. Heart valve prosthesis consisting of a substantially rigid frame with provided therein several synthetic membranes whereby the membrane is a fibre-reinforced matrix material, characterised in that the fibres are arranged parallel in the matrix material and that the fibre material and the matrix material are chemically identical.

2. Heart valve prosthesis as claimed in claim 1, characterised in that the matrix material and the fibre material consist of polyether urethane.

3. Heart valve prosthesis as claimed any one of the claims 1-2, characterised in that for the production of the fibre material is used polyether of a lower molecular weight than for the preparation of the matrix material.

4. Heart valve prosthesis as claimed in claim 3, characterised in that for the preparation of the fibre material is used polyoxy tetramethylene glycol of a relatively low molecular weight relative to the polymer for the matrix material.

5. Method for producing a heart valve prosthesis as claimed in claim 1, characterised in that in a mould in the shape of the assembly of membranes a solution of the matrix material is applied and dried to form a film of matrix material, the fibres are arranged parallel on the film and the frame is placed and finally a matrix film is formed in one or more operations so that the fibres are embedded and the membrane is adherent to the frame.

6. Heart valve prosthesis as claimed in claim 1, whereby the heart valve is an aorta valve consisting of three membranes

connected to a frame, characterised in that the membranes have been produced according to a method as described in claim 5.

7. Heart valve prosthesis with a frame and three fibre-reinforced membranes suspended in the frame, said frame being sub-
5 stantially an upright, circular closed strip with three frame legs located along the strip at equal distance in the same direction, whereby the height of the strip is greatest near the frame legs and each time decreases symmetrically, according to a certain curve, from two frame legs along the strip to the centre of the strip portion between
10 the frame legs and whereby each time the coaptation portion of a membrane is connected to two adjacent frame legs and the free membrane portion is connected to the strip portion of the frame enclosed by the frame legs, whereby in the closed position of the heart valve prosthesis the coaptation portions of the membranes lie against each other and
15 the ends of the coaptation portions not connected to the frame legs define a substantially straight line, characterised in that the frame is substantially rigid, that the fibres in the membrane are spaced substantially parallel to each other and are substantially perpendicular to said line in the coaptation portion in the closed
20 position of the heart valve prosthesis, and that the membranes are connected directly to the frame.

8. Heart valve prosthesis as claimed in claim 7, character-ised in that the frame is made of steel.

9. Heart valve prosthesis as claimed in claim 8, character-
25 ised in that the thickness of the frame and the diameter of the frame legs are approximately 1 mm.

10. Heart valve prosthesis as claimed in any one of the claims 7-9, characterised in that the angle α of the free membrane portion to said line ranges from 0 to 20°.
30 11. Heart valve prosthesis as claimed in any one of the claims 7-10, characterised in that the modulus of elasticity of the fibres in the membranes ranges from 10 to 50 N/mm^2.

12. Heart valve prosthesis as claimed in any
35 one of the claims 7-11, characterised in that the matrix thickness of the membranes ranges from 0.2 to 0.6 mm.

13. Heart valve prosthesis as claimed in any one of the

claims 7-12, characterised in that the fibre thickness of the
membranes ranges from 0.2 to 0.3 mm.

14. Heart valve prosthesis as claimed in any
one of the claims 7-13, characterised in that the mean fibre
5   distance in the membranes ranges from 0.8 to 2.7 mm.

15. Heart valve prosthesis as claimed in claim 14, character-
ised in that the angle α approximately equals 10°, that the modulus
of elasticity is app. 50 N/mm^2 , that the matrix thickness of the
membranes is app. 0.4 mm, that the fibre thickness of the membranes
10   is app. 0.25 mm and that the average fibre distance in the membranes
is app. 1.5 mm.

16. Heart valve prosthesis as claimed in any
one of the claims 7-15, characterised in that the surface
area of the coaptation portion of the membranes ranges from
15   38 to 152 mm^2 and is preferably 76 mm^2.

17. Heart valve prosthesis as claimed in any
one of the claims 7-16, characterised in that the modulus of
elasticity of the matrix material of the membranes ranges from
1 to 5 N/mm^2 and is preferably app. 1.8 N/mm^2.
20   18. Mould for producing a heart valve prosthesis therein,
characterised in that the mould is shaped such that a heart valve
prosthesis can be produced as indicated in any one of the claims 7-17.
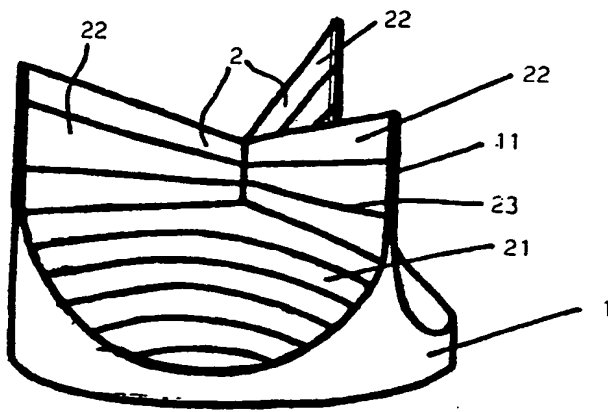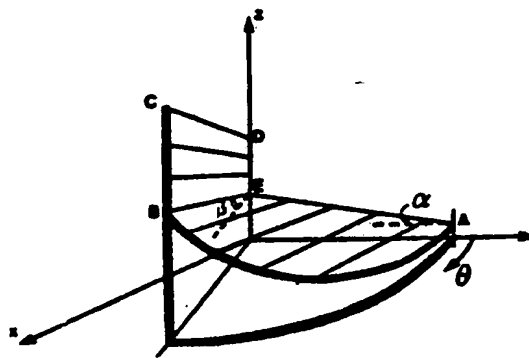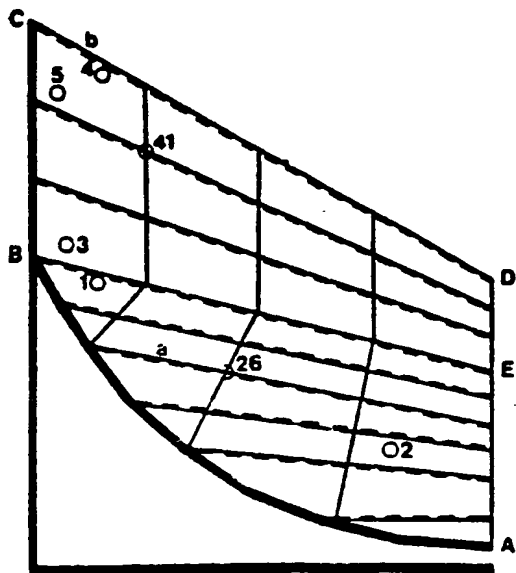
FIG. 1

FIG. 2

FIG. 3

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	US-A-4 265 694 (BORETOS et al.) * Column 6, lines 4-19; column 7, lines 1-7; figures *	1,7	A 61 F 2/24
A,D	BIOMEDIZINISCHE TECHNIK, vol. 26, no. 3, March 1981, pages 40-43, West-Berlin, DE; G. HÄUSSINGER et al.: "In-vitro Ergebnisse von Dauerfestigkeit und Hämolyse einer flexiblen Taschenklappe" * Page 41, paragraph 1 *	1,7	
A	US-A-4 340 091 (SKELTON et al.)		
A	US-A-4 345 340 (ROSEN)		

TECHNICAL FIELDS
SEARCHED (Int. Cl.4)

A 61 F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	30-05-1986	GLAS J.

EPO Form 1503 03.82